201-14551

Petroleum HPV

June 18, 2003

The Honorable Christie Whitman, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attention: Chemical Right-to-Know Program
HPV Consortium

Re: Response to Comments on the Waxes and Related Materials Test Plan

Dear Administrator Whitman:

The Petroleum HPV Testing Group is a consortium representing 92 percent of the nation's petroleum refining capacity. The Group is made up of 70 member companies of the American Petroleum Institute (API), the National Petrochemical & Refiners Association (NPRA), the Gas Producers Association (GPA) and the Asphalt Institute. The Testing Group appreciates the comments it received on its Test Plan for Waxes and Related Materials that was submitted to EPA on August 6, 2002 and posted on the Agency's ChemRTK website on August 22, 2002. The Environmental Protection Agency (EPA), Environmental Defense and the People for the Ethical Treatment of Animals (on behalf of several animal welfare organizations) submitted comments on the Test Plan. In the interest of communicating our intent with all interested stakeholders, the Testing Group is providing a revised Test Plan and robust summary for posting on the ChemRTK website. In addition, the two documents will also be posted on our website, www.petroleumhpv.org.

Environmental Defense agreed with the Testing Group's category rationale and proposed testing, so there are no responses in this letter directed specifically to Environmental Defense. The EPA and PETA comments did contain questions and observations that necessitate a response from the Testing Group. To summarize the major issues contained in the EPA and PETA comments and the Testing Group's responses:

Category Definition and Justification

EPA found the information in the test plan on the aromatic hydrocarbons content of slack wax to be contradictory. The Testing Group offers the following to clarify the seeming contradiction regarding the aromatic content of slack waxes.

> Generally, before slack wax is separated from a base oil fraction, the base oil undergoes some degree of solvent refining. This solvent refining lowers the aromatic content of both the base oil and the resulting slack wax. Hence the Testing Group's statement that slack waxes derived from solvent-refined vacuum distillates contain very low levels of alkylated aromatic hydrocarbons. The 34.7- 65.0% aromatic content of vacuum residuum noted in the next paragraph of the test plan represents the aromatic content of a base oil fraction before it has undergone solvent extraction and the accompanying reduction in aromatic content. Slack wax is not normally derived from such an unrefined vacuum residuum, but if it were, this would represent the upper bound for the aromatic content of a slack wax. The Testing Group included it in the test plan for just that purpose, to define the upper boundary for aromatics in the category.

EPA raised several issues with regard to the oil components of the waxes including whether these non-wax hydrocarbons will have physicochemical and environmental properties similar to the waxes.

> The Testing Group believes the EPA's questions regarding the oil components will be addressed in the Lubricating Oil Basestocks Test Plan that has been submitted to the EPA in March, 2003.

EPA found that the toxicological data presented in the test plan on repeat dose toxicity does not support the inclusion of paraffin (low melting point) and microcrystalline wax (high melting point) in a single subgroup of refined/finished waxes.

> The Testing Group continues to believe that given their process history and levels of residual oil and impurities, the two types of waxes are appropriately grouped into a single sub-category. Thus, the Testing Group views the results of the repeat dose toxicity studies as characterizing the boundary of a single sub-category, and not differentiating the materials into two separate sub-categories. Furthermore, the Testing Group is still of the opinion that the proposed testing of slack wax will address the hazards of both the paraffin and microcrystalline waxes (whether they are placed in one or two sub-categories), since slack wax, as the least processed of the materials contains the broadest spectrum of chemical components of all the categories of materials address in this program. For that reason, the toxicity of either the paraffin or microcrystalline waxes is expected to be less than that of the slack waxes.

Test Plan

Physicochemical Properties

EPA advised the Testing Group that it needed to provide boiling point data for slack wax and petrolatum and vapor pressure data for all the category members.

> Boiling points for slack wax and petrolatum are not available. However, because their constituent hydrocarbons are produced from vacuum distillation, they will have boiling points above 300°C. The Testing Group has revised the boiling point section of the robust summary to include language to that effect. Any vapor pressure attributable to these materials would be from the oil component of the material (if it is present). As discussed in the Lubricating Oil Basestocks test plan, the vapor pressures of lubricating base oils are expected to be negligible. The Testing Group has revised the vapor pressure of the robust summary to include language to that effect.

Environmental Fate Issues

The EPA is correct in noting that the hydrotreated slack wax (CAS 92062-09-4) referred to in the biodegradation section is not a member of this category.

> Although this specific slack wax process stream is not among the HPV-sponsored materials in this category, the hydrotreating procedure (i.e., removal of sulfur) does not substantially alter the component hydrocarbon character from the source slack wax material (CAS No. 64742-61-6), which is a member of this category. Consequently, the Testing Group thinks the material is similar enough to the slack wax in the HPV category that the degradation information can be used to categorize that endpoint. The Testing Group has included language to this effect in both the revised test plan and robust summary.

EPA also asked that biodegradation data for petrolatum be provided, since the Testing Group had judged the existing data to be “adequate.”

> The Testing Group believes read across from slack and refined waxes is adequate to assess the biodegradation of petrolatum. While there are no biodegradability studies on petrolatum, the Testing Group believes information on slack and refined waxes and the characteristics of the differing components of petrolatum provide a substantial body of evidence to assess the biodegradability of this product. In retrospect, the Testing Group recognizes that applying this data to petrolatum involves a read across. Therefore, the Testing Group is revising the data adequacy matrix in the test plan to indicate “read across” on petrolatum biodegradation. Furthermore, the Testing Group has revised the biodegradation sections of both the test plan and robust summary to clarify why the group judged the existing biodegradation data “adequate” and why the data could be read across to petrolatum

EPA notes that there is an apparent inconsistency in the listing of the methods used to test the ready biodegradability of the waxes (pages 7, 9 and 16 of the robust summary).

> The Testing Group has rechecked the methods and found the robust summary is correct, both the OECD 301B and 301F assays were used.

The Agency was critical of the model that the Testing Group had selected for developing environmental transport/distribution data (fugacity).

> After careful in-depth review, including contacting outside experts, the Testing Group decided that the use of the Level 3 model suggested by EPA for evaluating petroleum mixtures transport and distribution behavior is at this time, an inappropriate approach. The Testing Group reached this conclusion due to the lack of accurate emissions data and the limitations of using fugacity models originally developed for single chemicals to estimate the behavior of complex mixtures.

Health Effects

Refined/Finished Waxes. The EPA found the sections of the robust summary dealing with acute and repeated-dose toxicity endpoints to be inadequate. The adequacy of these data could not be determined because a single summary was submitted for a total of nine substances that were tested in a series of three studies.

> The Testing Group reviewed robust summaries for acute data and found no summaries discussing multiple test materials. Consequently, revisions were restricted to clarification of test material description, only. The Testing Group has revised the robust summary of the repeat dose study that was performed on three waxes and 6 oils. The Testing Group believes this revised summary will lead to a better understanding of the study design, the nature of the three waxes that were tested and the study results. EPA asked that the Testing Group revise the reproductive toxicity section of the robust summary to include relevant information on the histopathology of male and female reproductive organs for petrolatum and refined waxes. The attached revised robust summary includes all the histopathology information available to the Testing Group.

Ecological Effects

EPA suggested that data referenced from CONCAWE, 1997 indicating that no toxicity is expected from these chemicals should be brought forward to support the statement and enhance the technical discussion.

The Testing Group agrees with EPA regarding the CONCAWE, 1997 data, and has included an expanded discussion and summary table of the data in the revised test plan.

EPA asked that the Testing Group provide robust summaries of cited work by Adema and van den Bos Bakker (1986) and CONCAWE (1997) regarding the acute and chronic effects in aquatic organisms.

The Testing Group has included in the revised robust summary descriptions of both the Adema *et. al* study and the CONCAWE report.

Proposed Testing

PETA took issue with the Testing Group's plan to perform any testing on these materials. PETA believes "further chemical characterization and extrapolation of known toxicities on the components" would make additional toxicity testing unnecessary.

The EPA agreed with the Testing Group's proposal to conduct a bacterial gene mutation test and a combined repeated-dose/reproductive/developmental toxicity screening test on only one member of the category. The screening test will also include an *in vivo* evaluation of erythrocyte micronucleus formation. As noted in previous test plans, the Testing Group shares PETA's goal that the HPV Challenge Program be conducted in a manner that takes into account animal welfare concerns. In this regard, the Testing Group also shares PETA's desire to limit the amount of toxicity testing which is performed under this test plan. However, the Testing Group continues to believe that the testing it has proposed is necessary to characterize the SIDS level I mammalian toxicity of materials within the waxes and related materials category.

In support of not performing additional toxicity studies, PETA comments that 800 animals will be used in the studies proposed by the Testing Group. However, after carefully reviewing the proposed protocols, the Testing Group estimates the number of animals used in the test will be approximately 130, significantly less than the eight hundred PETA referenced in their comments.

With regard to mutagenic and carcinogenic potential of the category members, the Testing Group agrees with PETA that the PNAs are the "primary identified toxic compounds in the HPV test category". While the Testing Group assumes a similar relation exists between PNA content and potential reproductive and development toxicity, the existing database is not as robust as that which exists for carcinogenicity/mutagenicity. Given the seriousness of this endpoint, the Testing Group believes it is only prudent to evaluate this correlation by performing the screening test on slack wax – a material that will maximize possible effects.

PETA suggests the waxes and related materials and lubricating basestocks categories be combined.

The Testing Group understands that the intent of the PETA suggestion is to ensure the inter-relationships of the materials in these two categories are considered in developing test plans. The Testing Group also recognizes that the processing history, physico-chemical properties and potential toxicities of the materials included in these two categories are closely related. The Testing Group has taken these relationships into account when developing the test plans for the two categories. Consequently, the Testing Group believes it has, in practice, achieved the goal PETA hoped to achieve with its suggestion of combining the two categories.

PETA noted that there appeared to be a contradiction in the proposal to perform an *in vitro* bacterial reverse mutation assay and the Testing Group's rationale for conducting an *in vivo*

micronucleus test, “the physical/chemical nature of the test material precludes testing the intact material *in vitro."*

> The Testing Group agrees the wording for the mutagenicity test proposal could have been clearer, but still believes its decision is correct to perform both *in vitro* and *in vivo* studies. *In vitro* testing of relatively insoluble compounds, i.e. waxes, can be performed by using solvents to dissolve the test compounds. The solvents and the high solvent concentrations used in these *in vitro* assays are not acceptable to mammalian cells. Consequently, *in vitro* testing of these relatively insoluble materials is limited to bacterial assays. The Testing Group continues to believe mutagenicity data on mammalian cells is also necessary to complete the characterization of the mutagenic potential of these materials.

Specific Comments on the Robust Summaries

Physicochemical Properties

Melting Point. EPA asked that the melting point data presented in section 2.12 of the robust summary be incorporated into Section 2.1, MELTING POINT. In addition, EPA requested the melting point data be provided in robust summary format showing the method and source of the information.

> The Testing Group has revised the robust summary per EPA’s request.

Health Effects

Repeat Dose Toxicity. The EPA found inadequate the portion of the robust summary describing three 90-day GLP/OECD guideline toxicity assays for several kinds of refined/finished waxes in dietary-exposed rats.

> The Testing Group has revised the robust summary of the repeat dose study that was performed on three waxes and 6 oils. The Testing Group believes this revised summary will lead to a better understanding of the study design, the nature of the 3 waxes that were tested and the study results. The Testing Group disagrees with the EPA position that this summary includes 3 separate studies. Per the study design, the data presented are of series of “nested” studies, which the Testing Group believes are best considered as a package. To separate the studies into three separate robust summaries would be similar to separating the recovery group of a repeat dose study into a separate robust summary.

The Testing Group appreciates the EPA’s and PETA’s comments and interest in the waxes and related materials testing program. It believes that the revised Test Plan, being submitted via this letter, is both scientifically sound and meets the spirit of the EPA’s guidance on animal welfare. The revised Test Plan makes every effort to minimize the number of animals used in toxicity testing, while at the same time allowing the sponsors to fulfill their product stewardship responsibilities.

The revised Waxes and Related Materials Test Plan and Robust Summaries have been submitted electronically to the EPA ChemRTK and OPPT electronic mailboxes.

If you have further questions or comments about the program, please call me at (202) 682-8344, Tom Gray at (202) 682-8480 or visit our website at www.petroleumhpv.org.

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